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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,266	02/24/2004	Stephen Bennett Elliott	1119-002	9964

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WITHROW & TERRANOVA, P.L.L.C.
100 REGENCY FOREST DRIVE
SUITE 160
CARY, NC 27518

EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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01/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,266

Applicant(s)

ELLIOTT, STEPHEN BENNETT

Examiner

Mark W. Bockelman

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-46 is/are pending in the application.
- 4a) Of the above claim(s) 34-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-17-2007 has been entered.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because applicant's specification refers to figures 1-6 and the current version of the figures are labeled 100-600. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 requires a thought process for part of the invention. The method calls for a instructing a person to breath at a rate with the intent of achieving coherence. The intent is a thought process which cannot be determined for purposes of patentability.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Claims 21-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant's claim relies upon a thought process of intending to do something which constitutes non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-26, 32-33 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lehrer et al "Heart Rate Variability Biofeedback Increases Baroflex Gain and Peak Expiratory Flow". Lehrer et al teaches a method of instructing patients on page 800 "Procedure for HVR feedback". The method has the patient breath at different rates following a sinusoidal indicator while the physician analyzes a frequency spectrum to determine a resonant frequency. Then, the patient is sent home to practice the breathing exercises with the instruction of what frequency to practice, which is intended to be a resonant frequency. The physician adjusts the target rate around .085 hz (5 bpm). When the patient returns in two weeks, HRV biofeedback is carried out. During resonant frequency testing and practice, no biofeedback is performed. It would appear that only the physician sees the frequency range results for interpretation. In the home practice sessions no biofeedback is stated to be performed. Thus the examiner considers applicant's instructive method to be taught without biofeedback in the first two stages. While it is unclear as to whether the timing monitor used in resonant frequency determination is employed in the practice session, it would have been obvious to have included it to help practice the breathing rates. Applicant's range of breathing frequencies of "around about .085 hz" are taught (4.5- 6.5bpm) and to have provided and let applicant selected other types of signals rather than visual

would have been obvious to one of ordinary skill in the art. As noted by the examiner, there appears to be no feedback to the patient during the first two procedures and the examiner consider those procedures to teach the claimed method. If not inherent, it would have been obvious not to provide feedback since it is likely the patient would not understand the spectrum analysis or have any reason or need to understand it. With respect to claims 32-33, such is a function of the patient and no new steps are added to the method of claim 21.

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer et al "Heart Rate Variability Biofeedback Increases Baroflex Gain and Peak Expiratory Flow" in view of Schreiber USPN 6,212,135. To have provided alternative sensory type out puts such as lights and audible sounds and let the patient choose between the type of signal most pleasant to them would have been obvious in view of Schreiber. Schrieber teaches a device for a patient to follow in practicing inhaling and exhaling to a certain rhythm using either a light indicator or an audible indicator. Such type of indicators were well known at the time of applicant's invention as alternative signaling devices which merely provide a preference as to how the signal is transmitted and provides no improvement to the operation of the device.

Claims 21-26, 32-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schreiber USPN 6,212,135 alone, or alternatively in view of Lehrer et al "Heart Rate Variability Biofeedback Increases Baroflex Gain and Peak Expiratory Flow" or Vaschillo et al USPN 5,997,482.

Schrieber teaches a device for teaching breathing techniques upon the desire to lower breathing rate to as low as 1-2 breaths per minute. With very little practice the patient may achieve 8-9 bpm (column 1 lines 35-45). Slowly lowering the breathing rate down to 1-2 bpm would entail practicing with lower frequencies as the patient gets more comfortable with the method. Thus the target rate at least at some point will be around about .085 hz. The examiner gives no weight to the "intent" of the instructive method, however, and thus considers the method anticipated by Schrieber. Alternatively, to have pretested the patient using the Vaschillo technique of achieving resonance and providing that value to the patient to implement the Schrieber system would have been obvious.

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber USPN 6,212,135 alone, or alternatively in view of Lehrer et al "Heart Rate Variability Biofeedback Increases Baroflex Gain and Peak Expiratory Flow" or Vaschillo et al USPN 5,997,482. While Schreiber teaches his invention will work with a visual indicator or an audible indicator he does not teach the patient being able to select from one of the other. However, to have combined such signal alternatives to make the device useful to both blind and deaf patients would have been obvious to one of ordinary skill in the art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

January 7, 2008


MARK BOCKELMAN
PRIMARY EXAMINER